School of Pharmacy
Office of the Dean

1104 Salk Hall Pittsburgh, Pennsylvania 15261 412-648-8579 Fax: 412 648-1086

May 31, 2000

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Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852 00 JUN -1 A9:

Re: FDA Regulation of Over-the-Counter Drug Products Public Hearing

Docket Number 00N-1256

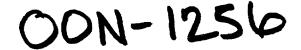
Dear Sir or Madam:

I am writing to request the opportunity to appear at the above referenced FDA public meeting concerning the regulation of OTC Drugs.

I served as the chair of the Nonprescription Drugs Advisory Committee (NDAC) from its inception in 1992 until the expiration of my term in 1996. This was a time of exceptionally high activity for the FDA in the consideration of Rx to OTC switch applications and other OTC drug issues. As a former member of the advisory committee, I have a perspective that I believe would be of value to the agency as it considers the multitude of issues raised in the announcement of this meeting.

After my service on the NDAC was completed, I was invited to assist several manufacturers in their preparation for advisory committee meetings. This has been enlightening for me as viewed from my primary perspectives as a pharmacist and University administrator. The nature of the industry and its impact on self-care is an important determinant in setting a regulatory framework for nonprescription products.

I consider myself an advocate for self-care and would appreciate the opportunity to express my views on this topic as they relate to the regulation of nonprescription drugs. Specifically, I would like to discuss the social and economic trends influencing consumer behavior in the self-care arena.



APE 36

The details of my request are:

Name:

Randy P. Juhl, Ph.D.

Dean and Professor, School of Pharmacy and

Associate Vice Chancellor for Research Conduct and Compliance

University of Pittsburgh

(412) 624-3270

Sponsor:

The Consumer Healthcare Products Association has agreed to

pay my expenses.

Time Requested:

20 minutes on Thursday, June 29, 2000.

(Please note: I will be in Atlanta on Wednesday, June 28, 2000, and will be unable to attend the meeting that day. I would greatly appreciate your accommodation in this regard.)

Thank you for your consideration.

Sincerely,

Dean and Professor